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| 23368 DINSMORE & | 7590 07/10/200 SHOHL LLP | EXAMINER | | |
| ONE DAYTON CENTRE, ONE SOUTH MAIN STREET | | | WILLIAMS, JAMILA O | |
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/822,386

Filing Date: April 12, 2004 Appellant(s): VIDLER ET AL.

> James F. Gottman For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4-24-2008 appealing from the Office action mailed 10-15-2007.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

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(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| 7,048,308 | BLANK | 5-2006 |
|-----------|--------------|---------|
| 4,549,750 | STONE et al. | 10-1985 |

(9) Grounds of Rejection

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The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4,13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over 7,048,308 to Blank.

Blank discloses a data carrier comprising a release liner (18), a health information label (14) having an upper and lower surface (figure 1 shows upper surface and figure 3 shows the lower surface) including a first area on the upper surface for indicia (area on the upper surface that includes "PHARMACY") and a second area on the upper surface for indicia (area on upper surface that includes "QUANTITY".

Blank discloses a pressure sensitive adhesive coating on the lower surface (adhesive 20) of the label securing the label to the release liner (figures 5 and 6) and a masking label integral with the health information label (32, see also figure 5 and column 4 lines 38-54 in that the label 32 can be removed and adhered to another object it is a masking label). A die cut in the release liner (18) defining a removable liner piece beneath the masking label (40), the removable liner piece being removable from the release liner with the health information label and remaining thereon when the health information label is applied to a surface (figure 3), the removable liner piece permitting the removal of the masking label from the label so that the masking label can be applied

over one or both of the first and second areas to obscure the association of identity of the patient and the health related information when the data carrier is discarded (see figure 5 and column 4 lines 38-54, in that the masking label 40 can be removed from the label 14 and adhered to another object, it is inherently capable of being applied to the first or second areas of label 14 via the adhesive 20).

Blank disclose the claimed invention except for the specific arrangement and/or content of indicia set forth in the claim(s). It has been held that when the claimed printed matter is not functionally related to the substrate it will not distinguish the invention from the prior art in terms of patentability. *In re Gulack*, 217 USPQ 401, (CAFC 1983). The fact that the content of the printed matter placed on the substrate may render the device more convenient by providing an individual with a specific type of information does not alter the functional relationship. Mere support by the substrate for the printed matter is not the kind of functional relationship necessary for patentability.

The examiner asserts that the data carrier comprising a release liner, label, adhesive, masking label, die cut, removable liner piece of Blank is the same structure claimed by applicant and the sole difference is in the content of the printed material. Thus, there is no novel and unobvious functional relationship between the printed matter (e.g. indicia) and the substrate (e.g. label), which is required for patentability.

Accordingly, there being no functional relationship of the printed material to the substrate, as noted above, there is no reason to give patentable weight to the content of the printed matter which, by itself, is non-statutory subject matter.

Regarding the limitations of the preamble, the data carrier of Blank is inherently capable of providing health related information regarding a patient and for facilitating compliance with HIPAA by obscuring the association between the identity of the patient and health related information when the data carrier is to be discarded, in that the structure of the data carrier is met by Blank and the arrangement and/or context of the indicia is addressed by In re Gullack above.

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Regarding claim 2, Blank discloses the first and second areas of are on a first portion of the label (the peripheral edge portions of the label, which is being defined as the portions where "PHARMACY" and "QUANTITY" are located in Blank) and the masking label is on a second portion of the label (the interior portion of the label, where 32 is located of Blank), the first and second portions being separated by a line of die cut perforations (38 of Blank).

Regarding claim 4, Blank discloses the pressure sensitive adhesive coating on the lower surface of the label comprises a permanent adhesive (Blank discloses that the label permanently bonds on the container in column 5 lines 33-35, therefore the adhesive 20 is inherently a permanent adhesive).

Regarding claim 13, Blank discloses a release liner (18), a first label (14) having an upper and lower surface, the label including a first and second area for indicia (see areas of "PHARMACY" and "QUANTITY"), pressure sensitive adhesive coating on the lower surface of the first label (adhesive 20), second label integral with the data carrier and defined by a die cut in the first label (second label 32), the second label configured such that upon removing the first label from the release liner, the second label remains

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with the first label when the first label is adhesively applied to a surface (figure 3) and when the second label is subsequently separated from the first label the second label is adapted to disassociate the identity of the patient from the health related information (in that the structure of the label is met by Blank, it is inherently capable of this function). Regarding the specific indicia, see the In re Gullack rejection applied to claim 1 above.

Regarding claim 15, Blank discloses the second label (32) is defined by a die cut (38) in the first label (14).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blank in view of 4,549,750 to Stone et al (hereinafter Stone). Blank discloses all elements of the claims but for the masking label being smaller than the removable liner piece beneath the masking label and the liner piece extending beyond the edge of the label such that the removable liner piece may be used to remove the masking label.

Stone teaches having a label (12 of Stone) with a removable liner piece (portion of liner 15 defined between score lines 16 in figure 2 of Stone), the removable liner piece extending beyond the edge of the label (see figure 1 element 18 and column 4 lines 3-5 of Stone). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the extending liner teaching of Stone with the removable liner and label of Blank for the purpose of allowing for easier removable of the label.

(10) Response to Argument

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Regarding Appellant's argument towards Blank and the In re Gullack "rationale" as applied to claims 1 and 4, the examiner maintains that the claimed data carrier is met by Blank.

The data carrier of Blank discloses a release liner (18), health information label (14) having upper and lower surface and including areas for indicia (see figure 1 or 3 and indicia associated therewith), a pressure sensitive adhesive coating (20) on the lower surface of the label, securing the label to the release liner (18) and a label (32 - in that this label can be removed from label 14 and adhered to another object it satisfies the limitation of being a masking label as claimed) integral with the health inforamtion label (14) and a die cut in the release liner (18) defining a removable liner piece (40) beneath the label (32), the removable liner piece being removable from liner 18 with the health information label (14) and remaining thereon when the health information label (14) is applied to a surface (container in figure 3), the removable liner piece (40) permitting the removal of the masking label (which 32 is being considered to be the masking label) from the health information label so that the masking label can be applied over one or both of the first and second areas of indicia (looking at figure 5 and column 4 lines 38 -54 of Blank, in that the masking label 32 with liner piece 40 can be removed from the label 14 and adhered to another object, it is inherently capable of being applied to the first or second indicia areas of label 14 as claimed).

The examiner takes the position that the sole difference between the Blank reference and the present invention is the arrangement and/or content of the printed matter. It has been held that when the claimed printed matter (first and second indicia or

functional relationship necessary for patentability.

indicia areas) is not functionally related to the substrate (label) it will not distinguish the invention from the prior art in terms of patentability. In re Gullack, 217 USPQ 401, (CAFC 1983). The fact that the content of the printed matter placed on the substrate (label) may render the device more convenient by providing an individual with a specific type of information (identity of patient or health related information) does not alter the functional relationship. Mere support by the substrate (label) for the printed matter (indicia areas for identifying the patient or health r elated information) is not the kind of

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As set forth above, the examiner asserts that the structure of Blank is the same and the different lies in the content of the printed matter. Thus, there is no novel and unobvious functional relationship between the printed matter (indicia) and substrate (label) which is required for patentability.

Blank meets the structures of the present invention and the sole difference is in the content of the printed matter.

Since the examiner finds that there is no functional relationship of the printed material to the substrate, altering the arrangement and/or content of the indicia (such that the first and second indicia areas on label 14 provide patient identity and health related information and the label 32 provides masking indicia for example) would have been obvious to one having ordinary skill in the art at the time the invention was made in light of the rationale of Gullack.

Appellant's arguments towards In re Ngai are also noted but this case and its particulars were not relied on in the action and therefore no further comment is provided herein.

Regarding appellant's argument towards the cut perforations of claim 2, the examiner maintains that 38 satisfies the claimed perforations between the first portion and second portions of the label (first portion having PHARMACY, QUANTITY written thereon) second portion defined by removable label portion (32).

Regarding appellant's argument towards the combination of Blank and Stone as applied to claim 6, the examiner maintains that Blank meets the structural limitations of the claims and the sole difference is the content of the printed matter which is met by the Gullack rationale detailed above. Stone is merely being provided to show a removable liner piece that extends beyond the edge of a label as recited in claim 6.

Regarding the appellant's separate argument towards claims 13 and 15, wherein applicant argues when the second label is separated from the first label, the second label is adapted to disassociate the identity of the patient from the health related information, the examiner maintains that Blank provides the label (14) having a removable label and liner portion (32,40) such that the removable label and liner portions (32,40) can be removed from the label (14) when attached to a container. In light of the Gullack rationale altering the arrangement/content of the indicia such that the identity of the patient is disassociated with the health related information on the label 14 would have been obvious.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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/J. W./

Examiner, Art Unit 3725

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